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| APPLICATION NO.                                                                     | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.             | CONFIRMATION NO.       |
|-------------------------------------------------------------------------------------|-------------|----------------------|---------------------------------|------------------------|
| 10/552,879                                                                          | 10/12/2005  | Terrence R Langford  | 122123.00004US1                 | 4467                   |
| 34282                                                                               | 7590        | 10/31/2007           |                                 |                        |
| QUARLES & BRADY LLP<br>ONE SOUTH CHURCH AVENUE, SUITE 1700<br>TUCSON, AZ 85701-1621 |             |                      | EXAMINER<br>DELCOTTO, GREGORY R |                        |
|                                                                                     |             |                      | ART UNIT<br>1796                | PAPER NUMBER           |
|                                                                                     |             |                      | MAIL DATE<br>10/31/2007         | DELIVERY MODE<br>PAPER |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

|                              |                        |  |                     |  |
|------------------------------|------------------------|--|---------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b> |  | <b>Applicant(s)</b> |  |
|                              | 10/552,879             |  | LANGFORD            |  |
|                              | <b>Examiner</b>        |  | <b>Art Unit</b>     |  |
|                              | Gregory R. Del Cotto   |  | 1796                |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 20 August 2007.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 14,15,18,20 and 27 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 14,15,18,20 and 27 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |                                                                                      |                                                                   |
|--------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____                                                          | 6) <input type="checkbox"/> Other: _____                          |

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### **DETAILED ACTION**

1. Claims 14, 15, 18, 20, and 27 are pending. Claims 1-13, 16, 17, 19, 21-26, 28, and 29 have been canceled. Note that, Applicant's arguments and amendments filed 8/20/07 have been entered.

### **Objections/Rejections Withdrawn**

The following objections/rejections as set forth in the Office action mailed 5/29/07 have been withdrawn:

The rejection of claims 14-20 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention has been withdrawn.

### ***Priority***

Note that, priority has been corrected.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

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(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 14, 15, 18, and 20 are rejected under 35 U.S.C. 102(e) as being anticipated by Hitchems et al (US 6,468,953). Note that, this rejection was necessitated by Applicant's amendment which broadened the scope of instant claim 14.

Hitchems et al teach the formation of antimicrobial solutions formed by ozonating a liquid containing organic precursor molecules. After ozonation is complete, the ozonated liquid may be diluted with water or other solvent to form a use solution for contacting and cleaning a microbially contaminated surface or other medium. See Abstract. Additives to the solution may include antimicrobial agents such as peroxygen-type disinfectants including peracetic acid, etc. See column 11, lines 30-65. The ozonated solution has a water to a water/ozonated solution ratio of between 1 and 100. See column 4, lines 30-55. The process of the invention incorporates a means to generate and dispense rinse water of high microbiological quality. Rinse water is generally applied as a final treatment step to remove solutions employed in the sanitation or cleaning processes. A suitable rinse solution can be made by directing ozone-enriched gas to a separate contactor chamber (i.e., tank), where the contactor contains an aqueous solution. Ozone is contacted with the water for a sufficient time to eliminate substantially all microorganisms from the water. The treated water is dispensed and directed to the item that has first been previously contacted with a cleaning or sanitizing solution. The disinfected rinse water removes excess disinfectant or cleaning agents. Moreover, the use of a rinse solution treated with ozone is preferably because ozone is a potent means of eliminating microorganisms from water

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and it decomposes rapidly without leaving a chemical residue. See column 14, lines 30-51.

The present compositions and methods of using the compositions are useful in the cleaning or disinfecting of equipment in the health care industries. Examples of items that can be disinfected include endoscope reprocessors, catheters, etc. See column 15, lines 12-30. Hitchems et al disclose the claimed invention with sufficient specificity to constitute anticipation.

Accordingly, the teachings of Hitchems et al anticipate the material limitations of the instant claims.

Claims 14, 15, 18, and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Langford (US 5,443,801) in view of Hitchems et al (US 6,468,953).

Langford teaches a cleansing/sterilizing apparatus which is a transportable apparatus and for inside-outside and sterilization of various complex reusable medical/dental instruments, including but not limited to laparoscopic instruments and dental handpieces. See Abstract. Specifically, Langford teaches filling a wash chamber and soaking the instruments with filtered ozonated water agitated by a peristaltic pump to denature any protein contaminants; draining the soak water by injecting sterile oxygen gas or sterile inert gas; washing the instruments with detergent in warm filtered water; draining the wash water by injecting sterile oxygen gas or sterile inert gas; rinsing the instruments with filtered ozonated water agitated by the peristaltic pump to sterilize all surfaces inside and out and to flush any remaining bio-debris; and draining the rinse water. The rinse cycle may be repeated multiple times. See column

21, lines 1-50. Note that, in Figure 17A, Langford teaches various chambers as well as outlets and inlets used in the process of cleaning and the Examiner asserts that this would suggest that the ozonated water used in the rinsing step of the cleaning process taught by Langford is ozonated, filtered water which has been stored in a receptacle such as a tank as recited by the instant claims.

Langford et al do not teach the specific amount of ozone in the water, the use of a chemical sterilizing agent such as peracetic acid or a method of cleaning and sterilizing a soiled item using the specific process steps including treating an item with a chemical sterilizing agent to achieve high level disinfection as recited by the instant claims.

Hitchems et al are relied upon as set forth above.

It would have been obvious to one of ordinary skill in the art, at the time the invention was made, to use water having the same volume of ozone as recited by instant claim 17, with a reasonable expectation of success, because Hitchems et al teach the use of ozone containing liquids having the same amount of ozone as recited by the instant claims for sterilizing medical instrument surfaces and further, Langford et al teach using ozone containing liquids for sterilizing medical instruments in general.

It would have been obvious to one of ordinary skill in the art, at the time the invention was made, to use an antimicrobial agent such as peracetic acid in the ozone rinse step in the process of sterilizing endoscopes taught by Langford et al, with a reasonable expectation of success, because Hitchems et al teach the use of peracetic acid as an antimicrobial agent in a similar process using ozone as a

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cleaning/disinfecting agent and further, the use of antimicrobial agents such as peracetic acid would be desirable because of the additional disinfection/sterilization properties provided by the use of peracetic acid in combination with ozone.

It would have been obvious to one of ordinary skill in the art, at the time the invention was made, to provide a final rinse of the disinfected item of Langford with ozonated, filtered water stored in a tank, with a reasonable expectation of success, because Hitchems et al teach the use of ozonated, filtered water stored in a tank as suitable for rinsing endoscopes in a similar disinfection process, and further, Langford teaches the use of filtered ozonated water as a rinsing agent in general.

It would have been obvious to one of ordinary skill in the art, at the time the invention was made, to sterilize a soiled item using the specific process steps including treating an item with a chemical sterilizing agent to achieve high level disinfection and providing a final rinse with ozonated filtered water stored in a tank as recited by the instant claims, with a reasonable expectation of success, because the broad teachings of Langford in combination with Hitchems et al suggest sterilizing a soiled item using the specific process steps including treating an item with a chemical sterilizing agent to achieve high level disinfection and providing a final rinse with ozonated filtered water stored in a tank as recited by the instant claims.

Claim 27 is rejected under 35 U.S.C. 103(a) as being unpatentable over WO02/32467.

'467 teaches an apparatus for cleaning medical equipment comprising a supply of filtered water, a supply of ozonated water containing a predetermined concentration

of water and means for delivering first a flow of filtered water over the surfaces of the equipment to be cleaned for a predetermined time followed by a flow of ozonated water over said surfaces for a predetermined time to disinfect the surfaces. See Abstract. The ozonated water is de-ionized prior to ozonating to the predetermined concentration. In the system, unozonated water was pumped through the system for 10 minutes and then ozonated water was pumped through the system for 6 minutes which achieves a high level disinfection. See page 6, lines 1-15. After the cycle, rinse water and ozonated water may also be flowed over the outer surface of the endoscopes to disinfect these as well. See page 7, lines 10-35. The apparatus comprises a means for filtering the tap water used in the process to provide a supply of filtered water.

Note that, the Examiner asserts that '467 teaches high-level disinfection and that it would have been obvious to one of ordinary skill in the art to run an endoscope through two or more cycles of high-level disinfection taught by '467 on instruments contaminated with hard to kill bacteria to ensure disinfection of the instruments. This type of disinfection which employs several cycles of disinfection is well known to those skilled in the art to thoroughly sterilize medical instruments or resterilize instruments immediately before use and would suggest rinsing an already cleaned and high-level disinfected item with water following by flushing the item with ozone as recited by the instant claims. Additionally, '467 teaches an apparatus for decontamination of medical equipment and the Examiner asserts that this apparatus would include a items and/or parts falling within the broad scope of a "chamber, a filter, a tray and a fill line" as recited by the instant claims which would desirably be flushed with ozonated water after

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cleaning the medical equipment to ensure disinfection and sterilization of the actual cleaning apparatus.

'467 does not teach, with sufficient specificity, a method of preventing recontamination of a cleaned and high-level disinfected item comprising rinsing the cleaned and high-level disinfected item with water following by flushing the apparatus with ozonated water as recited by the instant claims.

It would have been obvious to one of ordinary skill in the art, at the time the invention was made, to prevent recontamination of a cleaned and high-level disinfected item comprising rinsing the cleaned and high-level disinfected item with water following by flushing the item with ozone as recited by the instant claims, with a reasonable expectation of success, because the broad teachings of '467 suggest preventing recontamination of a cleaned and high-level disinfected item comprising rinsing the cleaned and high-level disinfected item with water following by flushing the item with ozone as recited by the instant claims.

### ***Response to Arguments***

Note that, at the outset, it should be noted that instant claim 14 has been broadened in scope by deleting several previously required process steps and that a new grounds of rejection has been made, as set forth above, using Hitchems et al which was necessitated by Applicant's amendment.

With respect to '801, Applicant states that there is no suggestion or disclosure to rinse the items with filtered, ozonated water stored in a tank so that biomatter resulting from the contamination of the water can be degraded as recited in claim 14 by the

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Applicant. In response, note that, as stated previously, the Examiner maintains that '801 teaches that the instruments may be rinsed with ozone and then water, followed by ozone again which suggests a final rinse step as recited by instant claim 14. While '801 may not specifically mention substantially degrading any remaining chemical residue and biomatter due to the rinse with ozone, the reason or motivation to modify the reference may often suggest what the inventor has done, but for a different purpose or to solve a different problem. It is not necessary that the prior art suggest the combination to achieve the same advantage or result discovered by applicant. Note that, while there must be motivation to make the claimed invention, there is no requirement that the prior art provide the same reason as the applicant to make the claimed invention. In re Linter, 458 F.2d 1013, 173 USPQ 560 (CCPA 1972). See MPEP 2144. The Examiner maintains that the ozone used in the rinse water taught by Langford would have the same biodegrading properties as recited by the instant claims.

Additionally, as stated above, note that, in Figure 17A, Langford teaches various chambers as well as outlets and inlets used in the process of cleaning and the Examiner asserts that this would suggest that the ozonated water used in the rinsing step of the cleaning process taught by Langford is ozonated, filtered water which has been stored in a receptacle such as a tank as recited by the instant claims.

With respect to '467, Applicant states that '467 does not describe or suggest flushing the sterilizing apparatus components including a chamber, a filter, a tray, and fill line with ozonated water after the completion of the high-level disinfection step. In response, note that, as stated above, '467 teaches an apparatus for decontamination of

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medical equipment and the Examiner asserts that this apparatus would include items and/or parts falling within the broad scope of a "chamber, a filter, a tray and a fill line" as recited by the instant claims. Further, the Examiner asserts that it would have been obvious to one of ordinary skill in the art to flush such parts and/or items with ozonated water after cleaning the medical equipment to ensure disinfection and sterilization of the actual cleaning apparatus. In other words, disinfecting the actual apparatus used to clean the medical equipment by flushing with ozonated water would be desirable and obvious to one of ordinary skill in the art so that the apparatus is sterilized and ready for the next use.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

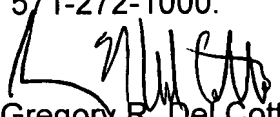
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gregory R. Del Cotto whose telephone number is (571) 272-1312. The examiner can normally be reached on Mon. thru Fri. from 8:30 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Harold Pyon can be reached on (571) 272-1498. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
Gregory R. Del Cotto  
Primary Examiner  
Art Unit 1796

GRD  
October 27, 2007